Risk Assessment Guidance for Superfund:

Volume III - Part A, Process for Conducting Probabilistic Risk Assessment

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DISCLAIMER

This document provides guidance to EPA Regions concerning how the Agency intends to exercise its discretion in implementing one aspect of the CERCLA remedy selection process. The guidance is designed to implement national policy on these issues.

Some of the statutory provisions described in this document contain legally binding requirements. However, this document does not substitute for those provisions or regulations, nor is it a regulation itself. Thus, it cannot impose legally-binding requirements on EPA, States, or the regulated community, and may not apply to a particular situation based upon the circumstances. Any decisions regarding a particular remedy selection decision will be made based on the statute and regulations, and EPA decision makers retain the discretion to adopt approaches on a case-by-case basis that differ from this guidance where appropriate.

Interested parties are free to raise questions and objection about the substance of this guidance and the appropriateness of the application of this guidance to a particular situation, and the Agency welcomes public input on this document at any time. EPA may change this guidance in the future.

ABOUT THE REVISION

WHAT IT IS

EPA's *Process for Conducting Probabilistic Risk Assessment* is an update of the 1989 *Risk Assessment Guidance for Superfund (RAGS)*. It is Volume III, an update to the existing two-volume set of RAGS. Volume III: Part A provides policy and guidance on conducting probabilistic risk assessment for both human and ecological receptors.

WHO IT'S FOR

RAGS Volume III: Part A is written primarily for risk assessors. Risk assessment reviewers, remedial project managers, and risk managers involved in Superfund site cleanup activities will also benefit from this addition to RAGS.

WHAT'S NEW

RAGS Volume III: Part A provides guidance on applying probabilistic analysis to both human health and ecological risk assessment. New information and techniques are presented that reflect the views of EPA Superfund program. A tiered approach is described for determining the extent and scope of the modeling effort that is consistent with the risk assessment objectives, the data available, and the information that may be used to support remedial action decisions at Superfund hazardous waste sites.

RAGS Volume III: Part A contains the following information:

- For the risk assessor— updated policies and guidance; discussion and examples of Monte Carlo modeling techniques for estimating exposure and risk.

- For the risk manager and the remedial project manager—an introduction to PRA, a chapter on communicating methods and results of PRA with the public, and a chapter on the role of PRA in decision making.

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ACRONYMS AND ABBREVIATIONS

1-D MCA	One-dimensional Monte Carlo analysis
2-D MCA	Two-dimensional Monte Carlo analysis
95% UCL	95% upper confidence limit
AM	Arithmetic mean
ARARs	Applicable or relevant and appropriate requirements
AT	Averaging time
AWQC	Ambient water quality criterion
BCa	Bias correction acceleration method
BMD	Benchmark dose
BMDS	Benchmark dose software
BMR	Benchmark Response
BTAG	Biological Technical Assistance Group
BW	Body weight
C	Concentration
CAG	Community advisory group
CDF	Cumulative distribution function
CI	Confidence interval
CIC	Community involvement coordinator
CIP	Community involvement plan
CLT	Central limit theorem
COC	Chemical of concern
CQR	Continuous quadratic regression
CSF	Cancer slope factor
CTE	Central tendency exposure
CV	Coefficient of variation
DI	Daily intake
DQO	Data quality objectives
EC_0	Exposure concentration that produces zero effect
EC_{20}	Concentration that causes a 20% effect
ECDF	Empirical cumulative distribution function
ED	Exposure duration
ED_{10}	Dose that causes a 10% effect
EDF	Empirical distribution function
EF	Exposure frequency
EPA	U.S. Environmental Protection Agency
EPC	Exposure point concentration
ERA	Ecological risk assessment
ERAF	Risk Assessment Forum
ERAGS	Ecological Risk Assessment Guidance for Superfund
EU	Exposure unit
EVIU	Expected value of including uncertainty
EVOI	Expected value of information
EVPI	Expected value of perfect information
EVSI	Expected value of sample information
GIS	Geographical Information Systems
GM	Geometric mean
GoF	Goodness-of-Fit
GSD	Geometric standard deviation
HEAST	Health effects assessment summary table
HHEM	Human Health Evaluation Manual

HI	Hazard Index
HQ	Hazard Quotient
IR	Iterative reduction
Irsd	Soil and dust ingestion rate
IRIS	Integrated Risk Information System
LADD	Life-time average daily intake
LCL	Lower confidence limit
LED_{10}	Lowest effect dose - lower confidence bound for dose that causes a 10% effect
LHS	Latin hypercube sampling
LOAEL	Lowest-observed-adverse-effect level
LOD	Limit of detection
LOEC	Lowest-observed-effect-concentration
MCA	Monte Carlo analysis
MCL	Maximum contaminant levels
MDC	Maximum detected concentration
MEE	Microexposure Event Analysis
MLE	Maximum Likelihood Estimation
MoMM	Method of Matching Moments
NCP	National Oil and Hazardous Substances Pollution Contingency Plan
NOAEL	No-observed-adverse-effect level
NOEC	No-observed-effect-concentration
OLS	Ordinary least squares
PBPK	Physiologically-based pharmacokinetic
PCBs	Polychlorinated biphenyls
pCi/g	Picocuries/gram
PDF	Probability density function
PDFu	Probability distribution for variability
PDFv	Probability distribution for uncertainty
PMF	Probability mass function
PPT	Parts per trillion
PRA	Probabilistic risk assessment
PRG	Preliminary remediation goal
PRP	Potentially responsible party
QAPP	Quality Assurance Project Plan
RAGS	Risk Assessment guidance for Superfund
RAL	Remedial action level
RBC	Risk based concentration
RCRA	Resource Conservation and Recovery Act
RfC	Reference concentration
RfD	Reference dose
RG	Remediation goal
RI/FS	Remedial Investigation/Feasibility Study
RME	Reasonable maximum exposure
RMSE	Root mean squared error
ROD	Record of decision
ROS	Rank order statistic
RPSS	Relative partial sum of squares
RPM	Remedial project manager
RSS	Regression sum of squares

SCM	Site conceptual model
SD	Standard deviation
SE	Standard error
SMDP	Scientific/Management Decision Point
SOW	Statement of Work
SR	Sensitivity ratio
SSD	Species sensitivity distribution
SSE	Sum of squares due to error
SSR	Sum of squares due to regression
SST	Sum of squares for total (regression plus error)
TAB	Technical Assistance to Brownfields Community
TAG	Technical assistance grant
TOSC	Technical outreach services for communities
TRV	Toxicity reference value
TSS	Total sum of squares
UCL	Upper confidence limit
VOI	Value of information

AUTHORS, CONTRIBUTORS, AND REVIEWERS

This manual was developed by EPA's Office of Emergency and Remedial Response. A number of individuals have reviewed and/or have been contributing authors of this document. Members of the EPA RAGS Volume III Workgroup, which was responsible for developing this document, included the following EPA headquarters and regional office staff.

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